

Application No. 09/720,278  
Paper dated December 13, 2005  
Response to Office Action dated June 13, 2005  
Attorney Docket No. 0702-002214

**RESPONSE UNDER 37 CFR § 1.116  
EXPEDITED EXAMINING PROCEDURE  
EXAMINING GROUP 1600**

**AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions, and listings, of claims in the application. Please amend Claims 1 and 11 as follows:

**Listing of Claims**

1. (Currently Amended): Medicament for treatment and/or prevention of infections and/or inflammation caused by ~~bacteria, fungi, viri and the like, inflammations and/or tumors~~ Candida species, said medicament comprising ~~an active amount of~~ a polycationic peptide or protein in an effective amount to treat said infections and/or inflammation, and a buffer in an amount of between about 0.5-100 meq H<sup>+</sup> for maintaining the pH of treatable tissue within a pre-selected range of about 5 to 8.5, wherein the polycationic peptide or protein is selected from the group consisting essentially of:

human lactoferrin, bovine lactoferrin, lactoferricin, conalbumin (ovotransferrin), ~~the polycationic peptides occurring in these proteins, and~~ hydrolysates of lactoferrin, ~~and cation rich peptides originating from lactoferrin;~~

polypeptide having an amino acid sequence selected from the following sequences (1)-(15), or derivatives thereof having an amide at the carboxy end thereof:

- (1) Arg-Trp-Gln-Trp-Arg;
- (2) Arg-Arg-Gln-Trp-Arg;
- (3) Lys-Val-Ser-Trp-Arg;
- (4) Arg-Asn-Met-Arg-Lys;
- (5) Arg-Trp-Gln-Glu-Lys;
- (6) Arg-Arg-Trp-Gln-Trp-Arg;
- (7) Arg-Arg-Arg-Gln-Trp-Arg;
- (8) Lys-Thr-Val-Ser-Trp-Arg;

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- (9) Lys-Arg-Asn-Met-Arg-Lys;
- (10) Arg-Trp-Gln-Glu-Met-Lys;
- (11) Lys-Thr-Arg-Arg-Trp-Gln-Trp-Arg-Met-Lys-Lys;
- (12) Lys-Ser-Arg-Arg-Arg-Gln-Trp-Arg-Met-Lys-Lys;
- (13) Lys-Thr-Val-Ser-Trp-Gln-Thr-Tyr-Met-Lys-Lys;
- (14) Lys-Thr-Phe-Gln-Trp-Gln-Arg-Asn-Met-Arg-Lys;
- (15) Lys-Thr-Leu-Arg-Trp-Gln-Asn-Glu-Met-Arg-Lys;

a peptide containing one of the following amino acid sequences (a), (b), (c), or (d):

\_\_\_\_\_S\_\_\_\_\_S\_\_\_\_\_

Lys-Cys-Arg-Arg-Trp-Gln-Trp-Arg-Met-Lys-Lys-Leu-Gly-Ala-

\_\_\_\_\_  
|

Pro-Ser-Ile-Thr-Cys-Val-; (a)

-Lys-Cys\*-Arg-Arg-Trp-Gln-Trp-Arg-Met-Lys-Lys-Leu-Gly-Ala-Pro-Ser-Ile-Thr  
-Cys\*-Val-: (b)

\_\_\_\_\_S\_\_\_\_\_S\_\_\_\_\_

Lys-Cys-Phe-Gln-Trp-Gln-Arg-Asn-Met-Arg-Lys-Val-Arg-Gly-

\_\_\_\_\_  
|

Pro-Pro-Val-Ser-Cys-Ile-; (c)

-Lys-Cys\*-Phe-Gln-Trp-Gln-Arg-Asn-Met-Arg-Lys-Val-Gly-Pro-Pro-Val-Ser  
-Cys\*-Ile-: (d)

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where Cys\* represents cysteine in which the thiol group is blocked in order to prevent disulfide bond formation and mixtures thereof and pharmaceutically and cytologically acceptable salts thereof;

a peptide consisting of one of the following specific amino acid sequences (a) - (l) or derivatives thereof having an amide at the carboxy end thereof:

- (a) Phe-Gln-Trp-Gln-Arg-Asn
- (b) Phe-Gln-Trp-Gln-Arg
- (c) Gln-Trp-Gln-Arg
- (d) Trp-Gln-Arg
- (e) Arg-Arg-Trp-Gln-Trp
- (f) Arg-Arg-Trp-Gln
- (g) Trp-Gln-Trp-Arg
- (h) Gln-Trp-Arg
- (i) Leu-Arg-Trp-Gln-Asn-Asp
- (j) Leu-Arg-Trp-Gln-Asn
- (k) Leu-Arg-Trp-Gln
- (l) Arg-Trp-Gln,

and lactoferrin hydrolyzate for the manufacture of antibacterial agent, ~~and chemical derivatives thereof, wherein by the derivatives, the polarity of the amino group of the amino acid residue constituting the protein is chemically modified into a negative moiety;~~

~~—— polycations belonging to the family of  $\alpha$  or  $\beta$  defensins, such as magainins, cecropins type A or B, protegrins, indolicidin analogs, polycations isolatable from insects, and histones;~~

mixtures thereof; and

pharmaceutically and cytologically acceptable salts of this group.

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2-3. (Canceled)

4. (Previously Presented) Medicament according to claim 1, wherein the polycationic peptide is lactoferrin.

5. (Previously Presented) Medicament according to claim 1, wherein the buffer is selected from the group consisting essentially of carbonate, phosphate, tromethamine, and tetrahydroxypyrrol ethylenediamine buffers, and/or suitable salts thereof.

6. (Previously Presented) Medicament according to claim 1, comprising at least 0.5  $\mu\text{mol}$ , and wherein the buffer is present in at least 1  $\mu\text{mol}$ .

7. (Previously Presented) Medicament according to claim 1, wherein the buffer is present in the range of 0.8-20 meq  $\text{H}^+$  per unit dose medicament.

8. (Previously Amended) Medicament according to claim 1, further comprising one or more of the following, standard excipients, dilutents and carriers.

9. (Previously Presented) Medicament according to claim 1, further comprising a standard anti-fungal, anti-bacterial, and/or antiviral agent selected from the group consisting essentially of azole compounds, 5-fluorocytosine, and polyenes.

10. (Previously Presented) Medicament according to claim 9, wherein the antifungal agent is present in the medicament in the range of 0.025 mg-50 mg.

11. (Currently Amended) Medicament for the treatment and/or prevention of infections and/or inflammation caused by bacteria, fungi, ~~vir~~ and the like, ~~inflammations and/or~~

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~~tumors~~ Candida species, said medicament comprising a polycationic peptide or protein being present in the medicament at a predetermined level in order to yield a synergistic pharmaceutical effect in combination with separately administerable bacterial, fungal and viral medicaments.

12. (Previously Presented) Medicament of claim 11 wherein the polycationic peptide or protein is selected from the group as defined in claim 1, and is present in the medicament in an amount of at least 10 mg/ml.

13. (Original) Medicament according to claim 12, further comprising one or more antifungal agents as defined in claim 9 and/or one or more excipients, diluents or carriers as defined in claim 8.

14. (Previously Presented) Medicament according to claim 13, wherein the anti-fungal agents are present in an amount of at least 0.1 mg/ml.

15. (Previously Presented) Medicament according to claim 1 and/or pharmaceutically acceptable salts thereof having one or more of the following forms: tablet, spray, salve, gel, liquid.

Claims 16-21. (Canceled)

22. (Previously Presented) A method for the treatment and/or prevention of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors whereby an effective amount of a composition according to claim 1 is administered to a patient.

23. (Withdrawn) Medicament according to claim 1, wherein the buffer maintains the pH of treatable tissue in the range of between about 7-8.

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24. (Withdrawn) Medicament according to claim 1, wherein the buffer is citrate salts.

25. (Withdrawn) Medicament according to claim 1, comprising at least 5 or more  $\mu\text{mol}$  polycationic peptide or protein, and wherein the buffer is present in at least 2 or more  $\mu\text{mol}$ s.

26. (Withdrawn) Medicament according to claim 1, further comprising a standard antifungal, anti-bacterial, and/or antiviral agent selected from the group consisting essentially of pimaricine, fungicide, and amphotericin B.

27. (Withdrawn) Medicament according to claim 1, further comprising a standard antifungal, anti-bacterial, and/or antiviral agent selected from the group consisting essentially of fluconazol, amphotericin B and 5-fluorocytosine.

28. (Withdrawn) Medicament according to claim 1, wherein the antifungal agent is present in the medicament in the range of between about 0.5-5 mg.

29. (Withdrawn) Medicament of claim 11, wherein the polycationic peptide or protein is selected from the group as defined in claim 1, and is present in the medicament in an amount of at least 20 mg/ml bodily fluid.

30. (Withdrawn) Medicament of claim 11, wherein the polycationic peptide or protein is selected from the group as defined in claim 1, and is present in the medicament in an amount of at least 60 mg/ml bodily fluid.

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31. (Withdrawn) Medicament of claim 11, wherein the polycationic peptide or protein is selected from the group as defined in claim 1, and is present in the medicament in an amount of at least 100 mg/ml bodily fluid.

32. (Withdrawn) Medicament according to claim 13, wherein the antifungal agents are present in an amount of at least 0.2 mg/ml.

33. (Withdrawn) In a medicament comprised of a polycationic peptide or a protein for treatment and/or prevention of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, the step comprising adding a buffer in an amount of between about 0.5 to 100 meq H<sup>+</sup> per unit dose medicament to the medicament to maintain the pH of a treatable tissue within a pre-selected range.

34. (Withdrawn) The medicament according to claim 33, wherein the buffer maintains the pH of treatable tissue in the range of between about 5 to 8.5.

35. (Withdrawn) The medicament according to claim 33, wherein the buffer maintains the pH of treatable tissue in the range of between about 7-8.

36. (Withdrawn) The medicament according to claim 33, wherein the buffer is selected from the group consisting essentially of carbonate, phosphate, tromethamine, and tetrahydroxypropyl ethylenediamine buffers, and/or suitable salts thereof.

37. (Withdrawn) The medicament according to claim 33, wherein the buffer is citrate salts.

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38. (Withdrawn) The medicament according to claim 33, comprising at least 0.5  $\mu\text{mol}$ , and wherein the buffer is present in at least 1  $\mu\text{mol}$ .

39. (Withdrawn) The medicament according to claim 33, comprising at least 5 or more  $\mu\text{mol}$  polycationic peptide or protein, and wherein the buffer is present in at least 2 or more  $\mu\text{mol}$ s.